Morphine Sulfate Injection

» Morphine Sulfate Injection is a sterile solution of Morphine Sulfate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of morphine sulfate pentahydrate [$(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O$]. Injection intended for intramuscular or intravenous administration may contain sodium chloride as a tonicity-adjusting agent, and suitable antioxidants and antimicrobial agents. Injection intended for intrathecal or epidural use may contain sodium chloride as a tonicity-adjusting agent, but contains no other added substances.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light. Preserve Injection labeled "Preservative-free" in single-dose containers.

Labeling—It meets the requirements for *Labeling* under *Injections* ⟨1⟩. Label it also to state that the Injection is not to be used if its color is darker than pale yellow, if it is discolored in any other way, or if it contains a precipitate. Injection containing no antioxidant or antimicrobial agents prominently bears on its label the words "Preservative-free," and includes, in its labeling, its routes of administration and the statement that it is not to be heat-sterilized. Injection containing antioxidant or antimicrobial agents includes in its labeling its routes of administration and the statement that it is not for intrathecal or epidural use.

USP REFERENCE STANDARDS ⟨11⟩**—**

USP Endotoxin RS

USP Morphine Sulfate RS

Identification—

A: Dilute with methanol, if necessary, a volume of Injection to obtain a solution containing 500 µg per mL. Apply 20 µL of this solution and 20 µL of a solution of USP Morphine Sulfate RS in a mixture of methanol and water (1:1) containing 500 µg per mL to a suitable thin-layer